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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,660	12/18/2000	Ganapati R. Mauze	10004415-1	3498

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AGILENT TECHNOLOGIES
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EXAMINER

CEPERLEY, MARY

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 12/16/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/740,660

Applicant(s)

MAUZE ET AL.

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 28-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: _____

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1) Applicant's election without traverse of Group I, claims 1-27, in Paper No. 5 is acknowledged.

Claims 1-27 have been examined on the merits in this Office action. Claims 28-31 are withdrawn from consideration as being directed to a non-elected invention.

2) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4) Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

5) Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, as not corresponding to the enabling written description of the invention as it is set forth in the specification.

The description of the invention as it is set forth in the specification requires that the "matrix", "surface coating", "protection layer", "quencher" and "ligand" have particular chemical and functional characteristics in order for the "encapsulation vesicle" to be useful in the disclosed FRET immunoassay. Claim 1 does not adequately address these requirements and thus does not correspond with the enabling written description of the invention. There is inadequate enablement in the specification for all types of "assays" (e.g. gas chromatographic, NMR, HPLC, gas detection, etc.) using all types of "matrices" (paper, metals, carbon nanotubes, etc.), all types of "surface coatings" (does not require the presence of any fluorescent donor or acceptor molecules) and all types of "ligands" (no requirement that the "ligand" have a receptor). In order to correspond with the enabling written description, at a minimum, claim 1

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must designate that the assay is of the FRET type and must recite the required chemical and functional characteristics of the "matrix" (page 6), "surface coating" (page 6), the "protection layer" (page 8), "quencher" (page 8), and the "ligand" (page 4); see also, pages 3 and 4 of the specification.

6) Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and confusing for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 1 is indefinite and unclear in the use of the terms "matrix", "surface coating", "protection layer", "quencher", and "ligand" for the reason that the claim fails to recite the required chemical and functional characteristics of these elements which are required for the use of the "encapsulation vesicle" in the disclosed FRET immunoassay. See also, paragraph **5)** above.

b) In view of the fact that claim 1 does not require that the assay be of the FRET type, it is unclear what type of "donor molecule" is intended in claim 7.

c) In claim 9, it is unclear what is meant by the terms "**leading to** a non-substituted or substituted phenanthroline" and "aryls" (how can a single variable, e.g. R_1 be multiple "aryls"?). Further, if each variable is independently selected from "H, alkyl, aryl, and aryls", moieties which are not substituted, how can the "phenanthroline" be "substituted"? See also, claim 12.

d) The term "said donor molecule" of claim 20 finds no antecedent basis in independent claim 1.

e) Claim 22 contains the limitation "a ligand attached to the protection layer" which is redundant with (d) of claim 1. It is also unclear from the use of the term "having" exactly where the "acceptor" molecule is located in the "vesicle". There is no indication of what the "acceptor molecule" is accepting or what the "donor molecule" is donating.

f) For claim 23, there is no antecedent basis in claim 1 for the term "the acceptor's absorption band overlaps with the emission band of the donor".

g) In claim 24, there is no antecedent basis in claim 1 for the term "the acceptor".

h) In claim 27, there is no antecedent basis in claim 1 for the term "the biomolecule".

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7) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8) Claims 1, 4, 5, 20, 21, and 23-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Hainfeld et al (U.S. 5,521,289).

Hainfeld et al describe a composition which anticipates the "encapsulated vesicle" of instant claim 1. Hainfeld et al describe a cluster comprised of gold (a "matrix having a surface") with a polymer coating (a "surface coating on said matrix") wherein the polymer is further stabilized (protected) by adding an additional polymer layer (a "protection layer encapsulating said surface coating for protecting said surface coating from a quencher molecule") and attaching a biomolecule (a "ligand attached to said protection layer"). See col. 7, lines 3-22 and 36-64; col. 8, lines 31-42. Note that the description of page 4, lines 14-17 of the instant specification requires only that the "protection layer" have the characteristic of "allowing energy to pass through it" which would be a characteristic of the outer polymer layer of the reference composition. The limitations of instant claims 4 and 5, i.e. the modification of the matrix surface by the addition of functional groups, are described at col. 8, lines 31-34 of the reference. For the claim 20 limitation "wherein said ligand attached to said protection layer further comprises an acceptor molecule" see col. 8, the formula of line 6 wherein "F" is a fluorescent moiety which is further defined at lines 21 and 22 and includes the "fluorescein" of instant claim 24. For the specific "biomolecules" of instant claims 25 and 27, see col. 8, lines 39-41 of the reference. The method of use limitation of instant claim 26 does not further limit the composition per se.

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9) Claims 1, 20, 21, and 23-27 are rejected under 35 U.S.C. 102(a) as being anticipated by Abbott et al (WO 00/32044).


Abbott et al describe a composition which anticipates the "encapsulated vesicle" of instant claim 1. See page 6, lines 19-28 of the reference which describes a particulate substrate (a "matrix having a surface") with a metal film layered thereon (a "surface coating on said matrix") and an organic layer attached to the metal film (a "protection layer") to which is attached a recognition moiety (a "ligand attached to said protection layer"). For the assay limitations of instant claims 21 and 26, see page 5, lines 25-26 of the reference. For the specific ligands and acceptor molecules of claims 20 and 23-27 see page 46, line 27 – page 47, line 6; page 48, lines 26 and 27; claim 38.

10) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached at (703) 305-3399. The fax phone number for responses to be filed BEFORE final rejection is (703) 872-9306. The fax phone number for responses to be filed AFTER final rejection is (703) 872-9307.

Questions which are NOT RELATED TO THE EXAMINATION ON THE MERITS, should be directed to **TC 1600 CUSTOMER SERVICE at (703) 308-0198**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

December 13, 2002


Mary E. (Molly) Ceperley
Primary Examiner
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